

## **REMARKS**

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action mailed February 9, 2004 (the "Office Action"). Claims 1-103 are pending in this application. Claims 1-11, 13-24, 26-38, 40-46, 48-62, 64-82 and 84-103 stand rejected. Claims 12, 25, 39, 47, 63 and 83 stand objected to.

Applicants have cancelled claims 1, 2, 7-9, 20-23, 33-37, 41-45, 47, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86, 88, 91 and 95 herein without prejudice. Applicants have amended the remaining claims to include recitations suggested by the Examiner to be allowable subject matter and/or to include the limitations of the base claim and any intervening claims as suggested by the Examiner to place the respective claims in condition for allowance. New claims 104-110 are added herein. Support for new claims 104-110 can be found in the specification at page 4, lines 22-24, among other places. Thus, support for these amendments and new claims is found in the language of the original claims, currently pending claims, and throughout the specification. Consequently, no new matter is added by these amendments and new claims and their entry and allowance are respectfully requested. The concerns raised by the Examiner in the Office Action are addressed below.

### **I. Sequence Listing**

Applicants appreciate the Examiner's indication that the Sequence Listing filed June 6, 2003 has been approved.

### **II. Objection to the Drawings**

The drawings stand objected to on the basis that "LUCIFERASE" is misspelled in Figure 42 (y-axis label) and Figure 43 (right-hand side). Applicants submit concurrently herewith corrected formal drawings for Figure 42 and Figure 43. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

### **III. Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 2, 3, 13, 14, 51, 71 and 74 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants have canceled claim 2 without prejudice, thereby mooted the rejection with regard to claim 2. Applicants have amended the

remaining rejected claims herein according to the Examiner's suggestions to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**IV. Provisional Rejection of Claims Under the Judicially Created Doctrine of Obviousness-type Double Patenting**

A. Claims 1-11, 13-24, 26-38, 40-46, 52-62, 64-73, 75-82, 84-89, 91, 92 and 94 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 103-122 of copending Application No. 09/873,757.<sup>1</sup>

Applicants have canceled claims 1, 2, 7-9, 20-23, 33-37, 41-45, 52, 54, 57, 59, 68, 70, 76, 77, 79 86, 88 and 91 without prejudice, thereby mooting the rejection with regard to these claims. A Terminal Disclaimer executed by Applicants' attorney is filed herewith, whereby any patent term for the present application extending beyond the term of allowed U.S. Patent Application Serial No. 09/873,757 (issued U.S. Patent No. \_\_\_\_\_) is disclaimed. Accordingly, Applicants believe this provisional rejection is overcome with regard to the remaining rejected claims, and respectfully request its withdrawal.

B. Claims 1-11, 13-24, 26-38, 40-46, 48-62, 64-73, 75-82 and 84-103 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 5-10, 15, 17, 19, 21, 23-26, 28-32, 42-46, 48-52, 54-57, 64-71, 73-135 of copending Application No. 09/873,777.<sup>2</sup>

Applicants have canceled claims 1, 2, 7-9, 20-23, 33-37, 41-45, 52, 54, 57, 59, 68, 70, 76, 77, 79 86, 88 and 91 without prejudice, thereby mooting the rejection with regard to these claims. A Terminal Disclaimer executed by Applicants' attorney is filed herewith, whereby any patent term for the present application extending beyond the term of allowed U.S. Patent Application Serial No. 09/873,777 (issued U.S. Patent No. 6,713,452) is disclaimed. Accordingly, Applicants believe this provisional rejection is overcome with regard to the remaining rejected claims, and respectfully request its withdrawal.

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<sup>1</sup> Attorney Docket No. 9233-62.

<sup>2</sup> Attorney Docket No. 9233-64.

C. Claims 1-9, 13-22, 26-36, 40-44, 48-60, 64-71, 75-80, 84-90 and 94 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 7-11, 16-30, 40, 41, 46-48, 50, 52 and 68-102 of copending Application No. 09/873,899.<sup>3</sup>

Applicants have canceled claims 1, 2, 7, 9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. A Terminal Disclaimer executed by Applicants' attorney is filed herewith, whereby any patent term for the present application extending beyond the term of allowed U.S. Patent Application Serial No. 09/873,899 (issued U.S. Patent No. \_\_\_\_\_) is disclaimed. Accordingly, Applicants believe this provisional rejection is overcome with regard to the remaining rejected claims, and respectfully request its withdrawal.

**V. Claim Rejections Under 35 U.S.C. § 103**

A. Claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,597,797 to Clark in view of U.S. Patent No. 5,349,052 to Delgado et al. (Delgado et al.) and the WO Patent Application 97/14740 (WO 97/14740). Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

B. Claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand further rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,057,292 to Cunningham (Cunningham) in view of Delgado et al. and WO 97/14740. As noted above, Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the

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<sup>3</sup> Attorney Docket No. 9233-54.

Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

C. Claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand further rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,359,030 to Ekwuribe (Ekwuribe) in view of Delgado et al and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

D. Claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand further rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ekuwuribe in view of Delgado et al. and WO 97/14740 as applied against claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94, and further in view of Harris et al. *J. Macromol. Sci. C25: 325-373* (Harris et al.). Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

E. Claims 1-9, 13-22, 26-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over European Patent Application 0 511 903 (EP 0 511 903) in view of Delgado et al. and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**F.** Claims 1-9, 13-22, 26-31, 33-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over EP 0 511 903 in view of Delgado et al. and WO 97/14740 as applied to claims 1-9, 13-22, 26-31, 33-36, 40-44, 48, 49, 51-60, 64-71, 75-80, 84-89 and 94 and further in view of Harris et al. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**G.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hinds et al. *Bioconj. Chem.* 11: 195-201 (Hinds et al.) in view of Delgado et al. and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**H.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,323,311 to Liu et al. (Liu et al.) in view of Delgado and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**I.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Krishnan et al. *Proceed. Int'l Symp. Control. Rel. Bioact. Mater.* 27:1038-1039 (Krishnan et al. article) in view of Delgado et al.

and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**J.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Krishnan et al. article in view of Delgado et al. and WO 97/14740 as applied against claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 and further in view of Harris et al. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**K.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Krishnan et al. 1999 Nat. Meet. Amer. Assoc. Pharm. Scient. (Krishnan et al. abstract) in view of Delgado et al. and WO 97/14740. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**L.** Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Krishnan et al. abstract in view of Delgado et al. and WO 97/14740 as applied against claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94 and further in view of Harris et al. Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86 and 88 without prejudice, thereby mooting the rejection with regard to these claims. Applicants

have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**VI. Claim Rejections Under 35 U.S.C. § 102**

A. Claims 1-9, 13-22, 26-36, 40-44, 52-60, 64-71, 75-80, 84-89 and 94, 95, 99 and 101-103 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Publication No. 2003/0050228 to Ekwuribe et al. (Ekwuribe et al.). Applicants have canceled claims 1, 2, 7-9, 20-22, 33-36, 41-44, 52, 54, 57, 59, 65, 68, 70, 76, 77, 79, 86, 88 and 95 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

B. Claims 76-80 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 97/14740. Applicants have canceled claims 76, 77 and 79 without prejudice, thereby mooting the rejection with regard to these claims. Applicants have amended the remaining rejected claims herein to include recitations suggested by the Examiner as being allowable subject matter, to address the Examiner's concerns. Accordingly, Applicants believe this rejection is overcome and respectfully request its withdrawal.

**VII. Claim Objections**

Claims 12, 25, 39, 47, 63 and 83 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have canceled claim 47 without prejudice thereby mooting the rejection to claim 47. Applicants have amended the remaining claims to depend directly or indirectly from claims that have been amended to include recitations suggested by the Examiner as being allowable subject matter. Accordingly, Applicants believe this objection is overcome and respectfully request its withdrawal.

The Office Action notes that claim 74 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph, and to include all the limitations of the base claim. Applicants have amended claim 74 to address the rejections under 35 U.S.C. § 112, second paragraph, and to depend indirectly from a claim that has been amended to include recitations suggested by the Examiner as being allowable subject matter. Accordingly, Applicants believe this objection is overcome and respectfully request its withdrawal.

#### **VIII. Supplemental Information Disclosure Statement**

Applicants submit concurrently herewith a Supplemental Information Disclosure Statement.

#### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Applicants assert small entity status for this application. A check in the amount of \$333.00 (\$43.00 independent claim fee; \$55.00 extension fee; \$180 Supplemental IDS fee; and \$55.00 Terminal Disclaimer fee, all for small entity) is enclosed. This amount is believed



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to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



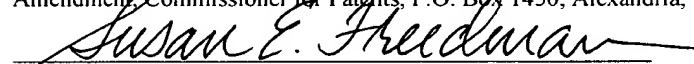
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Susan E. Freedman

Date of Signature: June 9, 2004